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# Blended CBT versus face-to-face CBT: A randomised non-inferiority trial

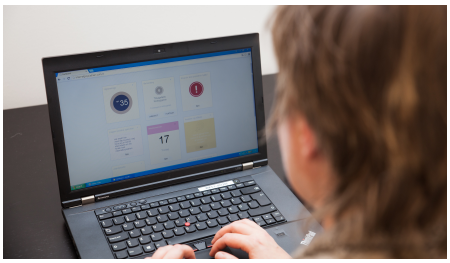
K. Mathiasen[1,2], Prof. H. Riper[3], Dr. T.E. Andersen[1], Dr. A.M. Kleiboer[3], Prof. K.K. Roessler[1]

1) Dept. of Psychology, University of Southern Denmark. 2) Centre for Telepsychiatry, Mental Health Services of Southern Denmark. 3) Dept. of Clinical Psychology, VU University of Amsterdam.

## Background

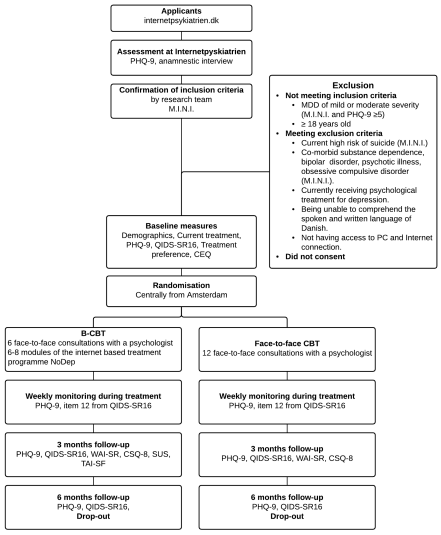
Depression is a prevalent and disabling disorder with high risk of relapse and great costs to the individual and to society[1,2]. Effective treatments exit, but there is a large gap between need and use of treatments[3]. One important contribution to bridge this gap comes from Internet based guided self-help (iCBT). In spite of its success, however, there is a need for increased therapist contact for some patient groups [4,5,6].

Combining iCBT with traditional face-to-face (ftf) consultations in a blended CBT format (B-CBT), in which both online modules and face-to-face consultations are combined in one coherent treatment manual may alleviate some of the difficulties associated with iCBT (such as lack of clinician contact), while still preserving some of the advantages of iCBT and ftf CBT alike.



## Aim

The primary aim of the present study is to compare the clinical effectiveness of blended cognitive behavioural therapy (B-CBT) for major depressive disorder (MDD) in adults with treatment as usual (TAU) defined as twelve sessions of face-to-face CBT. It is hypothesised that B-CBT will be as clinically effective as TAU, and that it will be acceptable and satisfactory to patients and clinicians.




## Methods

The study is designed as a two arm randomised non-inferiority trial comparing B-CBT for adult depression to treatment as usual (TAU). The present trial is affiliated to the EU-study E-COMPARED.

All participants must be 18 years of age or older and meet the diagnostic criteria for major depressive disorder (DSM-IV) and score 5 or higher on the Patient Health Questionnaire-9 (PHQ-9).

Participants are recruited from the Centre for TelePsychiatry in specialised mental healthcare at the Mental Health Services of the Region of Southern Denmark.

The primary outcome is analysed by regressing the 6-month follow-up PHQ-9 data on the baseline PHQ-9 score and a treatment group indicator. We will use an ancova model for this purpose. Missing values are handled using a full-information maximum likelihood estimator. In case of dropout, we will use the last observed values in a supplementary intention-to-treat analysis. Missingness sensitivity will be assessed with a best-/worst-case comparison, where missing values are replaced with the minimum and maximum values observed at follow-up.

## Why B-CBT?

Prominently, by providing ftf sessions, the therapist can individualise the therapy. Secondly, since B-CBT only provides half the number of ftf sessions as traditional CBT, the capacity of the treating clinician is increased. Additionally, the burden and cost of travel by the patient is reduced. Thirdly, the online modules are available at the time and place needed by the patients - and they can be re-viewed multiple times. Fourthly, the inherently structured format of the online modules secures equity of treatment to all patients. Finally, a principal barrier for the uptake of iCBT seems to be skepticism from clinicians[7], a barrier possibly alleviated by the blended format.

Few studies have investigated the use of blended care combining internet based psychotherapeutic modules and face-to-face sessions into one coherent treatment manual. Generally, however, they do indicate positive outcomes.

## Interventions

| Session number | Format of delivery | Content | Example of exercise |
|---|---|---|---|
| | | **B-CBT** | |
| 1 | F2F | Introduction and psychoeducation about depression and the treatment | Find a helper |
| 2 | Online module | Introduction to the programme, psychoeducation about depression, and goals for the treatment | Problem- goal list |
| 3 | F2F | Idiosyncratic model of the disorder | Cognitive case formulation |
| 4 | Online module | Psychoeducation about behaviour in depression | Activity registration |
| 5 | F2F | Accordance between personal values and behaviour. Introduction to cognitive restructuring. | Simple exercise for cognitive restructuring |
| 6 | Online module | Changing behaviour based on activity registration and personal values | Activity planning |
| 7 | F2F | Psychoeducation about negative automatic thoughts and cognitive restructuring. | Cognitive restructuring exercise |
| 8 | Online module | Psychoeducation about negative automatic thoughts and cognitive restructuring. | Cognitive restructuring exercise |
| 9 | F2F | Psychoeducation about behavioural experiments. Decision is made whether to include one or both of the extra modules | Behavioural experiment |
| 10 | Online module (A, B) | Behavioural experiments. (A: psychoeducation about core beliefs, B: coping with rumination) | Behavioural experiment (A: challenge core beliefs, B: test three techniques for coping with rumination) |
| 11 | F2F | Summing up, relapse prevention | Continuation of preferred exercises |
| 12 | Online module | Summing up, relapse prevention | Personal relapse prevention plan |
| | | **TAU** | |
| 1 | F2F | Introduction and psychoeducation about depression and the treatment | Find a helper |
| 2 | F2F | Psychoeducation and goals for the treatment | Problem- goallist |
| 3 | F2F | Idiosyncratic model of the disorder | Cognitive case formulation |
| 4 | F2F | Psychoeducation about behaviour in depression | Activity registration |
| 5 | F2F | Accordance between personal values and behaviour. Introduction to cognitive restructuring. | Simple exercise for cognitive restructuring |
| 6 | F2F | Changing behaviour based on activity registration and personal values | Activity planning |
| 7 | F2F | Psychoeducation about negative automatic thoughts and cognitive restructuring. | Cognitive restructuring exercise |
| 8 | F2F | Psychoeducation about negative automatic thoughts and cognitive restructuring. | Cognitive restructuring exercise |
| 9 | F2F | Psychoeducation about behavioural experiments. | Behavioural experiment |
| 10 | F2F | Psychoeducation about core beliefs or continue working on behavioural experiments | Challenge core beliefs or behavioural experiment |
| 11 | F2F | Psychoeducation about rumination or beginning of relapse prevention | Test three techniques to cope with rumination or start personal relapse prevention plan and continuation of preferred exercise |
| 12 | F2F | Summing up, relapse prevention | Personal relapse prevention plan |

## Discussion

It is a strength of the present study, that the treatments in the two conditions have similar therapeutic content given that both treatments are captured in one coherent treatment manual detailing each intervention. Consequently, the study will reveal a very direct comparison with a minimum of the variance explained by differences in therapeutic methods.
The study is limited, however, by the fact that even though it is situated in specialised mental health care, patients are recruited from a clinic offering self-referral. Consequently, the results may be hard to generalise with regards to future implementation.


## Contact

Kim Mathiasen
University of Southern Denmark
Email: kmathiasen@health.sdu.dk
Website: SDU.dk
Phone: +45 61 67 77 47

SDU

Centre for Telepsychiatry

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